MAY 0 2 2002

K021282

Appendix A - 510(k) Summary

Submitter

GUIDANT CORPORATION
Cardiac Rhythm Management
4100 Hamline Avenue
St. Paul, MN 55112

Contact: Michael Husby, Sr. Regulatory Affairs Associate
Tel: 651/ 582-5774, Fax: (651) 582-5134

Date

November 30, 2001

Device name

Device Trade Name:	LV-1 HEMOSTATIC VALVE
Device Common Name:	Hemostatic Valve
Device Classification Name:	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Device Classification:	Class II

Summary of substantial equivalence

The design, materials, method of operation, and intended use features of the GUIDANT LV-1™ Bleedback Control Valve are substantially equivalent to those of the predicate device, the GUIDANT COPILOT™ Bleedback Control Valve (K991102).

Device description

The LV-1 HEMOSTASIS VALVE, Model 6789 is a delivery system accessory for use in the implant of a GUIDANT left ventricular (LV-1) lead through the coronary sinus. The tip of the valve attaches to the LV-1 lead terminal pin and maintains a seal. A side arm port allows the lumen seal to be flushed and a bleedback control seal allows the introduction of an appropriately sized guide wire through an inside diameter of 0.070" (1.8 mm) while providing a seal.

The bleedback control seal is a diaphragm seal that forms around a guide wire as it moves into and out of the lead lumen, catheter, and vasculature. This seal restricts fluid loss without significantly inhibiting wire movement. The bleedback control seal is easily penetrated by the wire guide, a small plastic funnel accessory that facilitates the introduction of a guide wire.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2002

Ms. Karen S. Alsop
Pr. Regulatory Affairs Associate
Guidant Corporation
4100 Hamline Avenue N
St. Paul, MN 55112

Re: K021282
Trade Name: LV-1 Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold fitting
Regulatory Class: Class II (two)
Product Code: DTL

Re: K021283
Trade Name: Guidant Balloon Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO

Re: K021284
Trade Name: EASYTRAK® Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: DQY

Re: K021285
Trade Name: HI-TORQUE® Guide Wires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: April 17, 2002
Received: April 18, 2002

Dear Ms. Alsop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosures) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include

requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Appendix C - Indications for Use Statement

Applicant: GUIDANT CORPORATION

510(k) Number (if known): K021282

Device Name: LV-1 HEMOSTASIS VALVE

Indications for Use:
The LV-1 Hemostasis Valve with the Wire Guide is indicated for maintaining a seal around the LV-1 lead terminal pin while flushing the lead lumen and/or during introduction/withdrawal of interventional devices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021282